

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/06/2011

FORM APPROVED

OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  155324		(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		(X3) DATE SURVEY COMPLETED 08/16/2011	
NAME OF PROVIDER OR SUPPLIER  MITCHELL MANOR				STREET ADDRESS, CITY, STATE, ZIP CODE HIGHWAY 37 AT HIGHWAY 60 MITCHELL, IN47446			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE
F0000	<p>This visit was for the Investigation of Complaint IN00094593. This visit resulted in a partially extended survey, immediate jeopardy.</p> <p>Complaint IN00094593-Substantiated, Federal and State Deficiencies related to the allegations are cited at F 329.</p> <p>Survey Dates: August 15, 2011 Extended date: August 16, 2011</p> <p>Facility number: 000217 Provider number: 155324 AIM number: 100289590</p> <p>Survey team: Marla Potts, RN, TC Melinda Lewis, RN</p> <p>Census bed type: SNF/NF- 83 Total-83</p> <p>Census payor type: Medicare- 14 Medicaid- 59 Other- 10 Total- 83</p> <p>Sample: 3</p>			F0000			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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F0329 SS=J	<p>This deficiency also reflects state findings cited in accordance with 410 IAC 16.2.</p> <p>Quality review completed on August 17, 2011 by Bev Faulkner, RN</p> <p>Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used in excessive dose (including duplicate therapy); or for excessive duration; or without adequate monitoring; or without adequate indications for its use; or in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or any combinations of the reasons above.</p> <p>Based on a comprehensive assessment of a resident, the facility must ensure that residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.</p> <p>Based on interview and record review, the facility failed to ensure they developed and implemented a policy and procedure</p>			F0329	<p>This plan of correction is prepared and executed because of the provisions of State and federal law require it and not because Mitchell Manor agrees</p>		08/25/2011

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	<p>to effectively evaluate and establish parameters for the administration of Vancomycin, which included monitoring labs and communicating abnormal lab results related to Vancomycin therapy to the attending physician, for 1 of 3 residents reviewed for IV medications, in that a resident was given IV Vancomycin (antibiotic), after lab results showed he had critical levels of the medication and pharmacy recommended the medication be held, resulting in the resident experiencing acute kidney injury most likely secondary to Vancomycin and requiring dialysis. Resident A</p> <p>The Immediate Jeopardy began on 7/28/11 when Resident A's lab results concerning his Vancomycin therapy was high, not reported to the physician or orders obtained and the medication again administered on 7/29/11, resulting in kidney injury and dialysis. The Administrator and Director of Nursing were notified of the Immediate Jeopardy at 1:30 P.M. on 8/15/11. The immediate jeopardy was removed on 8/16/11, but noncompliance remained at the lowered scope and severity of isolated, no actual harm, with potential for more than minimal harm, that is not immediate jeopardy.</p>				<p>with the allegations and citations listed. Mitchell Manor maintains that the alleged deficiencies do not jeopardize the health and safety of the residents, nor is it of such character so as to limit our capabilities to render adequate care. Please accept this plan of correction as our credible allegation of compliance, that the alleged deficiencies cited have been or will be corrected by the date(s) indicated. To remain in compliance with all federal and state regulations, the facility has taken or will take the actions set forth in the following Plan of Correction.F 3291. Resident affected by alleged deficient practice: Resident returned from hospital without IV medications or Dialysis. 2. Residents at risk to be affected by alleged deficient practice: Residents receiving IV medication titrated per pharmacy/physician have the potential to be affected by the alleged deficient practice. Plan of care for residents with IV medication titrated per pharmacy/physician were reviewed by nursing admin and any notification completed at that time. Nursing admin educated licensed nursing staff August 15 th , 2001 regarding IV medication titrated per pharmacy/physician as well as physician notification on August 3 rd , 2011. Audit completed of all residents</p>		

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	<p>Findings include:</p> <p>Resident A's clinical record was reviewed on 8/15/11 at 10:30 A.M. The resident's diagnoses included but were not limited to "osteomyelitis." (infection of the bone)</p> <p>A Physician order, dated 7/21/11, indicated "Vancomycin 800 mg IV every 8 hrs [hours] x's [times] 6 weeks dx [diagnosis] osteomyelitis... Vanc [Vancomycin] peak and trough with every 3rd dose..." Another telephone physician order, dated 7/21/11, indicated "pharmacy to titrate vanc (Vancomycin) doses."</p> <p>A Vancomycin trough level dated 7/23/11, indicated a level of 16.7.</p> <p>A Pharmacist Dosing Recommendations form, dated 7/23/11, indicated "...Current IV Medication- Vancomycin 800 mg Q8H [every 8 hours]... Change to dose recommended below: Recommended dose: 1500 mg Q12H [every 12 hours]. **Obtain Trough level prior to 4th dose** Please consult with physician on the recommendation and fax a telephone order to the IV Department with these changes...." The form indicated for Vancomycin trough, the range of 16 to 20 was appropriate for osteomyelitis.</p>				<p>receiving labs with 100% compliance.</p> <p>3. Systems to ensure alleged deficient practice does not recur: Ongoing education with licensed nurses will be provided as indicated for non-compliance regarding follow-up concerning IV medication titrated per pharmacy/physician by nursing admin and/or Executive Director. Flow sheet implemented to record pertinent monitoring regarding IV medication that require titration by pharmacy/physician. Nursing admin will audit all IV medications that require dose recommendation from pharmacy/physician M-F x 3 months. Daily clinical review in Change of Condition Meeting, M-F by nursing admin will be updated to reflect IV medications that require dose recommendation per pharmacy/physician and completed at that time.</p> <p>4. Monitoring to ensure alleged deficient practice does not recur: Plan to be updated as indicated. Nursing admin will review residents on IV medications that require dose recommendation from pharmacy/physician daily M-F in Change of Condition Meeting to ensure documentation and follow-up. Unit manager/and or charge nurse is responsible daily to validate initiation of "Pharmacy Dosage Recommendation Flow</p>		

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	<p>A Physician order, dated 7/23/11, indicated "...Vancomycin (antibiotic) 1500 mg per IV q [every] 12 hrs [hours] draw vanc [Vancomycin] trough after 3rd does (1/2 hr after admin [administration])."</p> <p>A Pharmacist Dosing Recommendation form, dated 7/25/11, indicated "Current IV Medication Order: Vancomycin 1.5 gm q 12h. Lab results: Trough: 22.8...DC [discontinue] current order. Change to recommendation below. New IV order: Vancomycin 1.5 gm [gram] qd [everyday]. Obtain Trough level (Vancomycin) prior to 7/28 does. Thursday..."</p> <p>The Nurses Notes, dated 7/25/11 at 5:00 P.M., indicated "Received results of Vancomycin trough. Trough level 22.8. (Name) NP [Nurse Practitioner] notified. New order received to d/c [discontinue] current vanc [Vancomycin] order et [and] start Vancomycin 1.5 gm [grams] IV qd [everyday]. Obtain Vancomycin trough prior to 7/28 dose."</p> <p>A Physician order, dated 7/25/11, indicated "Vancomycin 1.5 gm [grams] IV qd [everyday]. Obtain Vancomycin trough level prior to 7/28 dose."</p> <p>A Pharmacist Dosing Recommendations form, dated 7/28/11, indicated "...Current IV Medication Order: Vancomycin 1.5 gm</p>				<p>Sheet" on all residents requiring IV medication titrated per pharmacy/physician. Audits of all charts for documentation/follow-up of IV medication titrated per pharmacy/physician will be conducted by nursing admin M-F x 3 month. Executive Director to ensure PI compliance. Compliance to be 100%. 5. Date of compliance: August 25, 2011. *Request follow-up survey as soon as possible please.</p>		

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	<p>qd. Lab results: Trough: 35. DC current order. New IV order: Obtain a random level 7/29/11 AM..." The MAR (Medication Administration Record,) dated July 2011, indicated the Vancomycin was not administered at 8 A.M.</p> <p>The Nurses Notes, dated 7/28/11 at 3:30 P.M., indicated "Vancomycin trough level drawn from PICC line by (name) RN. Taken to (name) lab."</p> <p>A Physician order, dated 7/28/11, indicated "Redraw Vancomycin trough on 7/29/11."</p> <p>The Nurses Notes, dated 7/28/11 at 9:00 P.M., indicated "Dr (name) in to see. Resident's right leg very red up to groin warm et resident states is painful to the touch...New orders received..." Telephone physician orders, dated 7/28/11, included orders for a venous doppler and cough medication written by the attending physician and an order to redraw Vancomycin trough on 7/29/11 from the Nurse Practitioner, NP #1.</p> <p>A progress note, dated 7/28/11, written by the attending physician, indicated "asked to eval by nurse, worsening leg, cough, occasionally refuses zosyn (antibiotic). The progress note did not include any</p>						

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	<p>information concerning the Vancomycin or lab results.</p> <p>The Nurses Notes, dated 7/29/11 at 8:30 A.M., indicated "Vanc (Vancomycin) trough drawn via PICC line and sent to (name) lab. Continues IV antibiotics for tx [treatment] osteomyelitis..."</p> <p>The July 2011 Medication Administration Record indicated on 7/29/11 at 8:00 A.M., LPN # 3 had given Vancomycin 1.5 gm IV.</p> <p>The Nurses Notes, dated 7/29/11 at 11:30 A.M., indicated "Vanc trough at 38.0 pharm [pharmacy] and NP aware. Orders to stop vanc dc [discontinue] at this time. Random vanc Monday AM Chem 7 stat after Zosyn (antibiotic) dose infused."</p> <p>The Nurses Notes, dated 7/29/11 at 1:30 P.M., indicated "Chem 7 drawn via PICC and sent to (name) lab via (name) p/u [pick up]."</p> <p>The Nurses Notes, dated 7/29/11 at 4:10 P.M., indicated "Called lab levels from Chem 7 to NP due to BUN at 31 [normal range 9 -20] Creat [creatinine]5.5 [normal range 0.8 to 1.5]. NP to consult Dr (name) and return call."</p> <p>The Nurse Notes, dated 7/29/11 at 4:30</p>						

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	<p>P.M., indicated "New orders from NP due to elevated bld [blood] levels sent to (name) ER [emergency room] via ambulance. Report called to (name) in ER. DON [Director of Nursing] aware of orders. (Name) ambulance here to p/u [pick up] resident at 4:55 P.M."</p> <p>A hospital History and Physical, dated 7/29/11, indicated "...On 07/21/2011 BUN was 9, creatinine 0.9. The patient was found to have on 07/29/2011 at Mitchell Manor a BUN of 31, and creatinine 5.5. I note on 07/28/2011, a Vancomycin trough level was 35.8. Vancomycin trough level on 07/29/2011 was 38. I do not have any other Vancomycin levels. It is unclear if they were done. He was initially on Vancomycin 800 IV every 8 hours from 07/21/2011 to 07/23/2011 and 1.5 grams IV every 12 hours from 07/24/2011 to 07/25/2011. I believe he has continued to receive Vancomycin from this, but it is difficult to figure it out from records sent...Acute kidney injury, most likely secondary to Vancomycin. Discussed with the patient he will need to be initiated on dialysis, both for his creatinine clearance, as well as for removal of his Vancomycin, which is significantly elevated still. He will undergo daily dialysis. I discussed with him hopefully this will be temporary but there is a chance this could be long-term..."</p>						



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	<p>The ADON (Assistant Director of Nursing) provided an investigation, which she indicated was conducted after discovering Resident A had received Vancomycin IV on 7/29/11. A time line labeled "Resident A" included: "7/28/11, 1.) (name of LPN #1) talked with (name of pharmacy) about increased vanc (Vancomycin) level 35.8 (name of pharmacy) requested to hold Vanc and get redraw thought it might be contaminated. 2.) 2:06 p.m.-recommendation came through fax machine. 3.) RN #2 redrew Vanc level in afternoon. 4.) During report from days to evenings (Name of LPN #1) reported to oncoming nurse (LPN #2) Vanc was held and to redraw level. 5.) Dr (residents primary care physician) in at 11 p.m. -saw resident-2nd shift nurse told him vanc was on hold -Nurse practitioner was present- he said ok. 6.) 7/29/11 day shift nurse reported upon receiving vanc level from the blood draw that levels have increased-Nurse practitioner (NP) notified-NP stated to (name of LPN #3) Vanc on hold -LPN #3 had given the 8 a.m. dose there was nothing written on the MARs (Medication Administration Record) to hold med no physician order to hold medication, no documentation on chart from day shift on the 28th, Chem 7 was drawn after Zosyn (antibiotic) dose infused at 1:30 p.m.</p>						

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	<p>-results received 3:30 p.m. increased BUN and creatinine levels (kidney functions levels), NP notified-sent to ER 4:55 p.m. received 8-2-11 H &amp; P from Hospital diagnoses acute kidney injury secondary to vanc. Implemented 1-(name of LPN #1) suspended 7/29/11 for no documentation of res condition...8/3/11 terminated (name LPN #1) terminated related to no documentation and MD notification."</p> <p>During interview with the ADON on 8/15/11 at 11:30 A.M., she indicated LPN #1 had not documented anything for her shift on 7/28/11. She indicated the lab and pharmacy had phoned and spoke with LPN #1 with nothing documented that day at all. ADON further indicated the 24 hour shift report did not include any information concerning the resident's Vancomycin levels.</p> <p>A written statement from LPN #1, dated 7/29/11, included: "spoke with pharmacy, Vancomycin level 35.8. IV department thought maybe level was incorrect as last level was lower and medication dose had been reduced...spoke to second shift nurse, asked her to finish orders for resident that RN #1 would draw lab for her. That MD was returning that evening and would need to see labs and give orders for antibiotics. Nurse stated she</p>						

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	<p>would. Returned to nurses station and attached note to MD resident list asking for ATB orders...."</p> <p>A written statement from LPN #2, dated 7/29/11, indicated " on 7/28/11 I came to work at approximately 2:20 p.m. ...LPN #1 stated that (name of Resident A) Vancomycin trough was 35.8 and I asked 'so his vanc's on hold' she stated yes and told me that his trough needed redrawn that afternoon 7/28 and for me to grab RN #1 ...also stated Resident A refused his zosyn and that Dr (primary care Dr) was coming in and to make sure that I had his vitals and chart ready when Dr came in that night...lab specimen obtained and sent to lab...at approximately 9 p.m. Dr (primary care Dr) was in the building. I approached him and asked him to see Resident A because of his leg, stated he would see him...I went to desk Dr still charting in chart and (Name of Nurse practitioner) NP 1, had came in as well. Dr asked about Vancomycin informed Dr and NP1 that resident's trough was 35.8 and vanc on hold. Asked if they wanted the vanc and trough done on 7/29/11 as per pharmacy recommendation had said. NP 1 stated to draw it on 7/29/11. I wrote the order to draw vanc trough on 7/29/11 and put it on the MARs...I gave report to LPN #4...told her trough of 35.8 and that NP1 said to redraw vanc trough on</p>						

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	<p>7/29/11 before administering next dose..."</p> <p>During interview with LPN #3, on 8/15/11 at 1:00 P.M., she indicated on 7/29/11 she only received in report that Resident A was ok. Nothing was passed on to her about the Vancomycin level. She indicated she administered the Vancomycin IV and then received the high lab results from the Vancomycin trough that a.m. LPN #3 indicated she called the pharmacy for recommendations as NP1 in the past had requested they call pharmacy first and then let her know what pharmacy said. LPN #3 indicated the pharmacy told her they had recommended the drug not be given the day before. LPN #3 indicated she then called NP1 who indicated the medications should not have been given. LPN #3 indicated there was no system where nurses would check the last lab on titrated antibiotics before giving the medication.</p> <p>During phone interview with Nurse Practitioner 1, NP1, on 8/15/11 at 1:15 p.m., she indicated she had heard LPN #2 state on 7/28/11 while she was in facility with the attending physician the Vancomycin was on hold. NP1 indicated she had spoke with the physician about this following the event and neither her nor the attending physician was told of the high Vancomycin level from 7/28/11, nor</p>						

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	<p>asked what to do with the Vancomycin. She indicated when she heard the nurse state it was on hold she assumed the physician had been asked what to do and ordered the medication held. NP1 further indicated the medication should not have been given with the labs that high.</p> <p>On 8/15/11 at 11:15 A.M., RN # 2 provided an inservice she had done with the nursing staff on 8/3/11. The inservice was titled Physician notification of Pharmacy Recommendations. The inservice indicated "...Pharmacy notifications must be reported to the physician with [sic] 24 hours, as usual. The exception to this would be if the notification were for HOLDING a med [medication] or STOPPING a med due to lab values. This instance would again be IMMEDIATE notification because it represents a need to alter treatment AND a significant change." RN # 2 indicated this inservice was done as a walking inservice. She indicated she had spoke individually with each nurse.</p> <p>On 8/15/11 at 11:15 A.M., RN # 2 provided the policy and procedure, "Blood Sampling for Peak and Trough Values," dated 3/3/10. She indicated this is available to all nurses in the The Nurses' Infusion Manual for Long Term Care Facilities. The policy indicated</p>						

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  155324		(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		(X3) DATE SURVEY COMPLETED 08/16/2011	
NAME OF PROVIDER OR SUPPLIER  MITCHELL MANOR				STREET ADDRESS, CITY, STATE, ZIP CODE HIGHWAY 37 AT HIGHWAY 60 MITCHELL, IN47446			
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	<p>"...Many medications must remain within a certain therapeutic range in the bloodstream in order to achieve desired effects. In some cases the level of medication in the blood may go beyond an acceptable limit and symptoms attributable to drug toxicity can develop. Therefore, monitoring certain drug levels is important...Proper dosing of aminoglycoside drugs and Vancomycin is important to achieve sustained serum concentrations and to prevent resistance, progression of infection and mortality...The "trough" is a measurement of drug in the blood right before the next dose and at its lowest level of concentration in the blood. Ideally just prior to infusion...Verify physician order/pharmacy recommendations for blood sampling...."</p> <p>The facility drug book, 2011 Lippincott's Nursing Drug Guide, was provided by the Assistant Director of Nursing, on 8/15/11 at 1:30 P.M. The book indicated "...Vancomycin...Geriatric patients or patient with renal failure. Monitor dosage and serum levels very carefully..."</p> <p>The Immediate Jeopardy that began on 7/28/11 was removed on 8/16/11, when the facility demonstrated policies and procedures had been put in place to ensure</p>						

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

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FORM APPROVED

OMB NO. 0938-0391

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	<p>staff were knowledgeable of the need to monitor labs and notify the physician., but noncompliance remained at the lowered scope and severity of isolated, at no actual harm, with potential for more than minimal harm, that is not immediate jeopardy.</p> <p>\</p> <p>This federal tag relates to Complaint IN00094593.</p> <p>3.1-48(a)(3)</p>						